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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/541,033	03/31/00	MILLER	R 35828-0079

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HM12/0504

EXAMINER

ROARK, J

ART UNIT	PAPER NUMBER
1644	9

AIR MAIL

DATE MAILED:

05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/541,033	Applicant(s) MILLER ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 20) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment, filed 3/1/01 (Paper No. 8), is acknowledged.

Claims 1-11 are pending.

2. Applicant's election without traverse of species of rheumatoid arthritis; an stressor of above body temperature and electromagnetic emission and oxidative environment; and TNFR:Fc in Paper No. 8 is acknowledged.

Claims 1-11, with respect to these elected species, are under consideration in the instant application.

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior applications in the first sentence of the specification (37 CFR 1.78).

4. Applicant's IDS, filed 8/3/00 (Paper No. 5), is acknowledged.

Applicant is required to provide a full citation, including a source and publication date, for the following references: 1) "Treatment Schedule..." 2) "Genetic Engineering News" 3) "Chen YL, Eur. J. Pharmacol."

5. The abstract of the invention is not descriptive. A new abstract is required that is clearly indicative of the invention *to which the claims are directed*.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

7. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

8. The specification and claims are not in permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).

Applicant should file a substitute specification to correct this problem. The substitute specification filed *must be accompanied by a statement that it contains no new matter*. Such statement must be a verified statement if made by a person not registered to practice before the Office. If a substitute specification is filed, Applicant should amend the substitute specification *to incorporate all previous amendments*. In addition, Applicant must indicate if the amendments have been incorporated into the substitute specification. (see 37 CFR 1.125).

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 6 is indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of ..." with the use of the conjunction "and". See MPEP 2173.05(h).

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolton (US Pat. No. 5,980,954, IDS) in view of Jacobs et al (US Pat. No. 5,605,690).

The claims are drawn to a method of treating a subject suffering from rheumatoid arthritis by administering the therapeutic treatment of p75 TNFR:Fc and autologous blood exposed to an oxidative environment, electromagnetic emission, and a temperature above body temperature.

Jacobs et al. teach and claim a method of lowering the levels of active TNF- α in a mammal having arthritis by administering a TNF antagonist, including TNFR:Fc (see entire document, especially claims and Examples 4-6). Jacobs et al. further teach the specific therapeutic treatment comprising TNFR:Fc p75 TNFR:Fc (e.g., Examples 1 and 2 in conjunction with columns 2-3 "Definitions"). Jacobs et al. further teach that a combination therapy of TNFR:Fc and another composition that also mediates a partial reduction in arthritis symptoms (rmu IL-1R) resulted in greater reduction of arthritis symptoms than did administration of either composition alone (see especially Example 4 at columns 17-18).

Jacobs et al. do not teach co-administering autologous blood exposed to an oxidative environment, electromagnetic emission, and a temperature above body temperature.

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Bolton et al. teach and claim a method of treating a subject suffering from rheumatoid arthritis by administering autologous blood exposed to an oxidative environment, electromagnetic emission (i.e., UV radiation), and a temperature above body temperature (see entire document, especially claims and Abstract). Electromagnetic emission is taught via a specific embodiment, UV radiation (e.g., claim 6-7 and column 8). Bolton et al. also teach that this method can be generally applied to a variety of autoimmune and inflammatory conditions, specifically including multiple sclerosis, scleroderma, diabetes, inflammatory bowel disease, psoriasis, atherosclerosis, and organ rejection (see especially column 9 at lines 29-40).

Given the teachings of the references that rheumatoid arthritis could be treated by administering either TNFR:Fc or autologous blood exposed to an oxidative environment, electromagnetic emission (UV radiation), and a temperature above body temperature; it would have been obvious to the ordinary artisan at the time the invention was made to combine the two treatments. The ordinary artisan would have been motivated by the teachings of Jacobs et al. that combination therapy is advantageous, to use these two treatments in the form of a combination therapy. Given that each treatment works individually, the ordinary artisan would have had a reasonable expectation of success with respect to the combination therapy. It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. In *re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. Further, the ordinary artisan at the time the invention was made would have recognized that the therapeutic treatment (i.e., TNFR:Fc) and modified blood could have been administered either simultaneously or consecutively while still functioning as a synergistic combination. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
May 3, 2001

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